

Application No.: 10/510,401
Filing Date: May 12, 2005

REMARKS

Claims 1, 3 and 10 have been amended. Claims 2, 11 and 12 have been canceled. Thus, claims 1, 3-10, 13-18 and 23-32 are now pending in the present application. Support for the amendment to claim 1 may be found in canceled claim 2, and in present claim 3. Support for the amendment to claim 3 may be found in the specification at page 9, lines 11-13. Support for the amendment to claim 10 may be found in canceled claims 11 and 12. Thus, no new matter has been added. Reconsideration and withdrawal of the present rejections in view of the amendments and comments presented herein are respectfully requested.

Interview Summary

Applicants' representatives would like to thank Examiners Badr and Hendricks for the courtesy extended to them during the telephonic interview conducted on March 2, 2010. The substance of this interview is reflected in the amendments and remarks presented herein and in the Interview Summary mailed March 29, 2010.

Rejection under 35 U.S.C. § 102(b)

The Examiner maintained the rejection of Claims 1, 6, 7, 9, 10, 13-16 and 18 as allegedly being anticipated by Klingenberg et al. (DD 156,714 A, referred to as "R1"). The Examiner contends that "although there is no explicit disclosure of preventing or retarding the staling during the baking process of the bakery products, given that R1 discloses method and improver identical to that presently claimed, it is clear that the method and improver would inherently prevent or retard staling during the baking process of the bakery products." Although Applicants strongly disagree with the rejection, claim 1 has been amended to recite the subject matter of claims 2 and 3 which were not rejected as being anticipated by Klingenberg et al. Clearly, the Klingenberg reference does not teach that the serine protease has a temperature activity optimum higher than 60°C, wherein said thermostable serine protease further has a ratio between the activity at optimum temperature and the activity at 25°C higher than 10, and that the protease is added in a sufficient amount to prevent or retard staling and to have substantially no effect on dough rheology.

Application No.: 10/510,401
Filing Date: May 12, 2005

In view of the comments presented above, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 102(b).

Rejections under 35 U.S.C. § 103(a)

Claims 3, 4, 8, 12, 17, 25, 27, 30 and 31 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Klingenberg et al. in view of Oleson et al. (US 6,110,508).

Claims 7 and 16 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Klingenberg et al. in view of Terada et al. (US 5,124,261) and Chernoglazov et al. (RU 2,177,799).

Claims 2, 5, 11, 23, 24, 26, 28 and 29 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Klingenberg et al. in view of Stetter (US 5,714,373).

In order for a claim to be rendered obvious, each element of the claim must be disclosed within the cited references. Present claim 1 as amended recites:

A method for the prevention or retarding of staling during the baking process of bakery products which comprises the step of adding an amount of at least one intermediate thermostable and/or thermostable serine protease to a dough prior to baking, wherein said serine protease has a temperature activity optimum higher than 60°C, wherein said thermostable serine protease further has a ratio between the activity at optimum temperature and the activity at 25°C higher than 10, wherein said amount is effective to prevent or retard staling in said bakery products and has substantially no effect on dough rheology

As an initial matter, Applicants note that there is no teaching or suggestion in the cited references that serine proteases having the recited properties can prevent or retard staling while having substantially no effect on dough rheology, nor is there any teaching or suggestion of using the serine protease in a sufficient amount to achieve these results.

The Examiner asserts that Klingenberg discloses a heat stable thermitase from *Thermoactinomyces vulgaris* and the use of the proteinase for weakening gluten in the preparation of wafers, other cereal and bakery products. As discussed below, Applicants do not concede that the crude enzyme preparations discussed in Klingenberg necessarily disclose serine proteases having the properties recited in the claims, nor do Applicants concede that Klingenberg

discloses dough for bakery products comprising the recited serine proteases. However, even if Klingenberg were to disclose proteases having the recited properties or dough comprising proteases having the recited properties, the disclosure of Klingenberg in combination with Oleson, Terada, Chernoglazov and Stetter would not preclude the patentability of the claimed methods.

Applicants note that 35 U.S.C. 101 defines four categories of inventions deemed to be the appropriate subject matter of a patent: processes, machines, manufactures and compositions of matter. The latter three categories define "things" or "products" while the first category defines "actions" (i.e., inventions that consist of a series of steps or acts to be performed). See 35 U.S.C. 100(b) ("The term 'process' means process, art, or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material."). (Emphasis added). Numerous court decisions also establish new uses for compositions described in the prior art are patentable. For example, in *Perricone v. Medicis Pharmaceutical Corp*, 432 F.3d 1368, 1378 (Fed. Cir. 2005), the Court of Appeals for the Federal Circuit (CAFC) stated "New use of old products or processes are indeed patentable subject matter." Additionally, in *In re Shetty*, 566 F.2d 81, 83 and 86 (CCPA 1977) the CCPA stated that a claim to a "method of curbing appetite in an animal which comprises administering to the animal an amount effective to curb appetite..." was patentable because prior art relating to the administration of structurally similar compounds did not suggest "a use, much less a dosage, for curbing appetite." Numerous other court decisions also support the principle that a new use for a known product is patentable.

In view of the lack of teaching or suggestion in Klingenberg or the other cited references that serine proteases can be used in a sufficient amount to prevent or retard staling while having substantially no effect on dough rheology, Applicants respectfully request that the rejection under 35 U.S.C. §103 be withdrawn.

Furthermore, Applicants maintain that Klingenberg teaches a crude enzyme preparation obtained from fermentation of *Thermoactinomyces vulgaris* which is alleged to contain a thermophilic protease (thermitase). This reference states that:

"[t]he enzyme thermitase being produced is suitable for use in various processes in the food industry as crude preparation or in partially purified form, and in highly purified form as fine biochemical. Fields of application are gluten breakdown in the production of processed foodstuff, waffles and bakery products."

However, Klingenberg does not describe any partially or highly purified forms of the thermitase.

Applicants note that the components of the crude preparation described in Klingenberg are undefined. Hence, it is not clear whether the preparation of Klingenberg necessarily contains serine proteases having the properties recited in the claims. Applicants submit that the crude preparation of Klingenberg contains numerous proteases/enzymes. Indeed, it is Applicants' understanding that *T. vulgaris* is known to encode at least five different proteases, including at least two metalloproteases (which are not serine proteases). It is unknown what the effects of adding the crude preparations described in Klingenberg to dough would be. In particular, it is not known whether such crude preparations could prevent or retard staling while having substantially no effect on dough rheology. Furthermore, as discussed above, there is no teaching or suggestion in Klingenberg of adding serine proteases having the recited properties to dough prior to baking in a sufficient amount to prevent or retard staling while having substantially no effect on dough rheology.

In the Office Action at page 3, section 4, the Examiner alleges that "given that R1 discloses method and improver identical to that presently claimed, it is clear that the method and the improver would inherently prevent or retard staling during the baking process of the bakery products." The Examiner is reminded that according to M.P.E.P. § 2112 IV, to support a rejection based on inherency, the Examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the characteristic alleged to be inherent by the Examiner **necessarily** flows from the teachings of the applied prior art. *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990). (emphasis added) "The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic." (emphasis added) *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is **necessarily present** in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.'" *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999). (emphasis added).

During the telephonic interview, the Examiners were of the opinion that the prevention or retarding of staling of a bakery product as recited in claim 1 was an inherent property of the thermostable serine proteases (which were asserted to be known in the art), and therefore disclosed by Klingenberg et al. However, there is no discussion in Klingenberg of any particular amounts of the thermitase which can be utilized in the contexts described therein, nor is there any discussion of preventing or retarding staling while having substantially no effect on dough rheology. As recited in present claim 1, the protease is added to the dough prior to baking in an amount effective to prevent or retard staling. The use of an effective amount of the recited serine proteases to prevent or retard staling while having substantially no effect on dough rheology, is a positive method step which is not disclosed or suggested, either inherently or otherwise, by any of the cited references. In fact, in *In re Shetty* discussed above, method claims reciting administration of a known compound in "an amount effective to curb appetite" were found patentable. *In re Shetty*, 566 F.2d 81, 83 (CCPA 1977) Thus, the cited references do not teach or suggest, the addition of an amount of thermostable serine protease effective to prevent or retard staling and which has substantially no effect on dough rheology.

The Examiner also insists that "[g]iven that the weakening of gluten is disclosed it is clear that the protease is added to the dough prior to baking as presently claimed." As noted in Applicants' previous response, Klingenberg et al. neither teaches nor suggests that the enzyme is added to the dough prior to baking as recited in present claim 1, because the thermitase could be used in the process of preparing a baked product without being added to the dough to be baked. The fact that gluten hydrolysis can occur without the addition of the hydrolyzing enzyme to the dough prior to baking is clearly supported by the Rule 132 Declaration filed with the previous response. The Examiner dismissed these arguments, stating that "weakening" of gluten by Klingenberg is "clearly indicative of the incorporation of the protease in the dough prior to baking", and that "the word "weakening" implies that the gluten in the dough is being addressed." However, the Examiner has not provided support for his position that the use of the terminology "weakening" necessarily means that the thermitase was added to the dough prior to baking. Without providing the basis for his position, which contradicts the statements in the Rule 132 Declaration, the Examiner cannot support a *prima facie* assertion of obviousness.

The Examiner also dismissed Applicants' arguments that it is unexpected that the claimed method would prevent or retard staling of bakery products. In particular, the Examiner asserts that "adding a protease and an amylase (involving proteins and starch) to bread dough is an old and known process in the art. Papain has also been implicated in retarding staling when added to the dough prior to baking bread." Office Action at page 8. As noted in the Rule 132 Declaration submitted with the previous response, at paragraph 10, other gluten-hydrolyzing enzymes are known (for example, papain and thermolysin), and these are not able to retard staling when added to bakery products without adverse effects on the dough or on the final baked product, more precisely on the structure of the crumb. Based on the inability of these enzymes to retard staling without adversely affecting the crumb structure, it would not be expected that serine proteases would be able to retard staling while having substantially no effect on the dough rheology. However, the present inventors have demonstrated that thermostable serine proteases unexpectedly result in an anti-staling effect in bakery products when added to the dough to be baked while having substantially no effect on the dough rheology. The Examiner provides no support for his contention that papain can retard staling without adversely affecting the crumb structure, which is contrary to the statements in the Rule 132 Declaration. Applicants note that the statements of experts as recited in such a declaration must be taken at face value unless the Examiner can provide evidence to the contrary. Thus, without providing the basis for his position, which contradicts the statements in the Rule 132 Declaration, the Examiner cannot support a *prima facie* assertion of obviousness.

In view of the comments presented above, Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. § 103(a)

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, the Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. The Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present

Application No.: 10/510,401
Filing Date: May 12, 2005

disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

CONCLUSION

Applicants have endeavored to address all of the Examiner's concerns as expressed in the outstanding Office Action. Accordingly, amendments to the claims, the reasons therefor, and arguments in support of the patentability of the pending claim set are presented above. In light of the above amendments and remarks, reconsideration and withdrawal of the outstanding rejections is specifically requested. If the Examiner finds any remaining impediment to the prompt allowance of these claims that could be clarified with a telephone conference, the Examiner is respectfully requested to initiate the same with the undersigned.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated: March 29, 2010

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